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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,797	12/04/2001	John David Fraser	55503-002001	9884

69713 7590 03/18/2010  
OCCHIUTI ROHLICEK & TSAO, LLP  
10 FAWCETT STREET  
CAMBRIDGE, MA 02138

EXAMINER
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JUEDES, AMY E

ART UNIT	PAPER NUMBER
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1644

NOTIFICATION DATE	DELIVERY MODE
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03/18/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/006,797	<b>Applicant(s)</b> FRASER ET AL.	
	<b>Examiner</b> AMY E. JUEDES	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-6, 10, 11, 13, 15-18, 21-26, 28-38 and 40-45 is/are pending in the application.
- 4a) Of the above claim(s) 17, 18, 21-26 and 28-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 10-11, 13, and 15-16 is/are rejected.
- 7) ☒ Claim(s) 6 and 40-45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment and remarks, filed 12/21/09, are acknowledged.  
Claims 6, 15-17, 21, 26, and 40-45 have been amended.  
Claims 2-6, 10-11, 13, 15-18, 21-26, 28-38, and 40-45 are pending.
2. Claims 17-18, 21-26, and 28-38 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.  
Claims 2-6, 10-11, 13, 15-16, and 40-45 are being acted upon.
3. The rejection of the claims under 35 U.S.C. 112 second paragraph is withdrawn in view of Applicant's amendment to the claims.
4. Upon reconsideration, and in view of Applicant's remarks, the rejection of the claims under 35 U.S.C. 103 is withdrawn.
5. Claims 6 and 40-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. The following are new grounds of rejection.
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:  
A person shall be entitled to a patent unless –  
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
8. Claims 2-5, 10-11, 13, and 15-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Hayball et al., Feb. 2000., as evidenced by Bannantine et al., 2004, and Invitrogen product information, 2008.

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Hayball et al. teach a SEB superantigen with a mutation in the T cell receptor contact site (see page 13, in particular). Hayball et al. teach that the superantigen is fused to polyhistidine (i.e. a protein/peptide antigen, see page 14, in particular). Hayball et al. teach that the superantigen fusion protein bind to MHC class II (see page 16, in particular). Additionally, SEB is a superantigen from *Staphylococcus aureus* (see page 14, in particular). Hayball et al. teach that the mutation in the TCR binding site is a deletion (see page 14, in particular). Hayball et al. teach that the SEB fusion protein is produced in a pTrcHis vector. As evidenced by Invitrogen product information, the pTrcHis vector contains a cleavage site for removal of polyhistidine (i.e. the polyhistidine is “reversibly” coupled). Furthermore, as evidenced by Bannantine et al., polyhistidine is non-immunogenic (see page 113, in particular). Additionally, Hayball et al. teach the superantigen conjugate as part of a composition suitable for incubation with cells, including as part of a composition comprising a 0.1% BSA/PBS solution (i.e. a pharmaceutically acceptable carrier, see page 14, in particular). Additionally, the recitation of a “vaccine” in claim 16 refers to an intended use of the claimed superantigen. The superantigen/His fusion protein of Hayball et al. is structurally identical to that of the instant claims, and would function as a “vaccine”.

Thus, the reference clearly anticipates the invention.

9. No claim is allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 8am to 4:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes

Patent Examiner

Technology Center 1600

/Amy E. Juedes/

Primary Examiner, Art Unit 1644